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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,478

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Bunshi Fugetsu

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EXAMINER

MCCRACKEN, DANIEL

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,478	Applicant(s) FUGETSU, BUNSHI	
	Examiner DANIEL C. MCCracken	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-10,24,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,10,24,31 and 32 is/are rejected.
- 7) ☒ Claim(s) 3 and 7-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Citation to the Specification will be in the following format: (S. # : ¶/L) where # denotes the page number and ¶/L denotes the paragraph number or line number. Citation to patent literature will be in the form (Inventor # : LL) where # is the column number and LL is the line number. Citation to the pre-grant publication literature will be in the following format (Inventor # : ¶) where # denotes the page number and ¶ denotes the paragraph number.

Status of Application

The finality of the office action dated 2/27/2009 is withdrawn in light of the Request for Continued Examination ("RCE") dated 7/27/2009. Claims 2, 4-6, 11-23, 25-30, and 31-32 are acknowledged as cancelled. Claims 1, 3, 7-10, 24, and 31-32 are pending with Claims 1 and 24 currently amended.

Response to Arguments & Remarks**Amendment to Specification**

Applicants have presented an amendment to the specification at pages 4 and 9, making certain grammatical corrections (introduction punctuation and the like). There was some issue as to whether "Gum Arabic" could properly be considered an alginate. One reading of the specification supported this construction. *See* (Advisory Action of 6/19/2009 at 2) ("Specifically, it is not understood whether Applicants contemplated "gum arabic" to be an "alginate" or not. The specification would appear to list "gum arabic" as an alginate. *See* (S. 4: 13-14) ("such as alginates, for example, alginic acid, propylene glycol alginate, gum arabic, xanthan gum..."). As

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such, the claims would appear to read on the Bandyopadhyaya reference.”). In response, Applicants have amended the Specification to insert punctuation that effectively precludes this construction of “Gum Arabic.” *See* (Amendment dated 7/27/2009). Such an amendment potentially raises issues of new matter, but upon consideration, does not do so here. Alginates are understood to be “a linear (unbranched) polymer in which regions have a predominance of either D-mannuronic acid with β -1,4 linkages or L-guluronic acid with α -1,3 linkages.” *See* Paul C. Silva, Richard L. Moe, "Alginate", in AccessScience@McGraw-Hill, <http://www.accessscience.com>, DOI 10.1036/1097-8542.022125 (accessed 9/16/2009). Gum Arabic, on the underhand, is understood to be “a highly branched arabinogalactan polysaccharide.” (Bandyopadhyaya at 27, n. 17). The correction to the specification appears to correct an error that would be recognized as obvious to one of skill in the art, familiar with the natural polymers (starches, celluloses, etc.) recited. As such, it is not being treated as new matter. The amendment to the specification makes maintaining the rejection over Bandyopadhyaya untenable.

Double Patenting, Claim Objections and
Claim Rejections – 35 U.S.C. §102-103, 112

Several rejections and objections were made in the Final Office Action dated 2/27/2009. For brevity's sake, it is not necessary to discuss each in detail except to state that they were either mooted by cancellation of the claims or by incorporation of non-rejected claims into independent claims (*i.e.* the surfactants of Claim 3 into independent Claims 1 and 24). Accordingly and as such, all rejections are WITHDRAWN. Newly discovered prior art is applied *infra*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I. Claims 24 and 31-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of Claim 24 is imprecise. Specifically, the actual process steps stop with “adding a crude product to an aqueous solution containing as an active ingredient to encapsulate the nanocarbon in the crude product.” The remaining language is a listing of compounds that do not further limit or describe the process steps – specifically the language does not describe or further limit the “active ingredient.” It appears as if Applicants are attempting to recite two different “active ingredients,” namely (i) certain surface active agents or (ii) alginates with a particular molecular weights.

The Examiner suggests using such language as: “wherein the active ingredient is a surface active agent [capable of forming globular micelles, etc.] selected from the group of consisting of [insert compounds] or alginates having a molecular weight of . . . , etc.” While there may be reasons for selecting which compounds to include or omit in this listing – *see* Claim Rejections, 35 U.S.C. 102 *infra* – language that clearly limits the “active ingredient” without introducing language that does not have support in the steps that precede it (*i.e.* “surface active agent”) would obviate this rejection. Dependent claims should be adjusted accordingly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

I. Claims 1, 10, 24 and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0152891 to Toone, et al.

This application apparently draws priority from a Japanese PCT filed on 6 December 2002. Note that Toone – while published on 14 July 2005 - draws priority from US Provisional application No. 60/377,862, filed on 3 May 2002. US Provisional filing dates can be relied upon for rejections under 35 U.S.C. 102(e). MPEP 2163.03 III states:

The 35 U.S.C. 102(e) critical reference date of a U.S. patent or U.S. application publications and certain international application publications entitled to the benefit of the filing date of a provisional application under 35 U.S.C. 119(e) is the filing date of the provisional application with certain exceptions if the provisional application(s) properly supports the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph.

MPEP 2136.03 III (emphasis added). Thus, Toone is prior art under 35 U.S.C. 102(e). A copy of said provisional application accompanies this office action, with references made to the provisional as appropriate in the following format: (Toone prov. page:line).

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With respect to Claim 1, Toone teaches an aqueous solution with carbon nanotubes (*i.e.* “nanocarbons”) and alginic acid (*i.e.* an alginate). Paragraph [0041] of Toone is reproduced below for convenience, with the passages being relied upon in boldface type.

[0041] Articles of the present invention also include pills and capsules comprising a pharmaceutically active agent and a coating or shell comprising one or more nanotubes containing nitric oxide or a gas with nitric oxide-like biological activity. Coated tablets of the invention can be prepared by a method comprising the step of contacting a tablet core comprising a pharmaceutically active agent with **a coating solution comprising a solvent, at least one coating agent dissolved or suspended in the solvent, one or more nanotubes**, and, optionally, one or more plasticizing agents. **Preferably, the solvent is an aqueous solvent, such as water or an aqueous buffer**, or a mixed aqueous/organic solvent. Suitable coating agents include beeswax, glyceryl monostearate, shellac, cetyl alcohol, mastic, stearic acid, cellulose, ethyl cellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate polymer, hydroxypropylcellulose, cross-linked sodium carboxymethylcellulose, microcrystalline cellulose, ethylcellulose, methylcellulose, cellulose acetophthalate, methylcellulose acetophthalate, cellulose acetate tetrahydrophthalate, cellulose acetopropionate, cellulose trimetallate, cellulose acetate, cellulose butyrate, carboxymethyl starch, starches, starch derivatives, polyvinyl acetate, carboxyvinylpolymers, polyvinylalcohol optionally cross-linked with glyoxal, formaldehyde, or glutaraldehyde, cross-linked polyvinylpyrrolidone, poly(methyl vinyl ethers-co-maleic anhydride), neutral copolymers of polymethacrylic acid esters (Eudragit L30D), copolymers of methacrylic acid and methacrylic acid methyl ester (Eudragits), a neutral copolymer of polymethacrylic acid esters containing metallic stearates, potassium methacrylate-divinylbenzene copolymer, acrylic and methacrylic copolymer, methyl methacrylate, methacrylic acid, ethyl acetate latexes, beta-cyclodextrine, dextrine derivatives, mannitol, lactose, sorbitol, xylitol, glucans, scleroglucans, mannans, galactomannans, carrageenan and derivatives thereof, xanthans, **alginic acid** and derivatives thereof, pectin, amylose, sandarac gum, and mixtures thereof. Suitable plasticizers include polyethylene glycol (PEG 200, PEG 1000), polyoxyethylene glycols, diethyl phthalate, dibutyl phthalate, triacetin, monoglyceride, rape seed oil, olive oil,

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sesame oil, acetyltributylcitrate, acetyltriethylcitrate, glycerin, sorbitol, diethyloxalate, diethylmalate, diethylfumarate, dibutylsuccinate, diethylmalonate, dioctylphthalate, dibutylsebacate, triethylcitrate, tributylcitrate, glyceroltributyrate, hydrogenated castor oil, fatty acids, substituted glycerides and triglycerides, glycerol, D-sorbitol, sucrose, mannitol, fructose, sugar alcohol, isomerized sugars, and propylene glycol. Typically, the tablet core is contacted with the coating solution until the weight of the tablet core has increased by an amount ranging from about 1% to about 20%, indicating the deposition of a suitable coating on the tablet core to form a coated tablet.

(Toone 5: [0041]) (emphasis added). This paragraph is found in the provisional application at (Toone prov. 13:6 – 14:12). Note that nanocarbons and the aqueous solutions are found at (Toone prov 13: 11-14) and alginic acid is found at (Toone prov. 14: 1). Given that Applicants recite “alginic acid” in their own specification as a suitable alginate with the molecular weight claimed and the micelle properties claimed— *see* (S. 9: 14) (“alginic acid”) – it is expected that the molecular weight and micelle property is necessarily present. As to Claim 10, the nanocarbons are nanotubes. *See* (Toone 5: [0041]; Toone prov. 13:6 - 14: 12).

With respect to Claim 24, the preceding discussion is relied upon. Note that Toone describes adding all three (nanocarbon, water and surfactant) together. *See* (Toone 5: [0041]) (describing contacting the coating agent, nanotube and coating agent). As to Claims 31-32, according to Applicants, alginic acid – taught by Toone at (Toone 5: [0041]) – is one of the surfactants of the claimed molecular weight capable of forming the globular micelles/pseudo micelles. *See* (S. 9: 1-19).

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Allowable Subject Matter

Claims 3 and 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Note however that rewriting Claim 3 as an independent claim is effectively the same as cancelling the “or which is alginate . . .” language from Claim 1, which would make Claim 3 objectionable for failure to limit the claim from which it depends. *See* 37 C.F.R. 1.75.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL C. MCCracken whose telephone number is (571)272-6537. The examiner can normally be reached on Monday through Friday, 9 AM - 6 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on (571) 272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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